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10/780,269

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EXAMINER

GILBERT, ANDREW M

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/780,269
Filing Date: February 17, 2004
Appellant(s): GRISPO, KEITH M.

James L. Johnson (Reg. No. 34,195)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/25/2011 appealing from the Office action mailed 5/24/2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:
57, 58, 68-80.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,471,674

Emig et al.

10-2002

Medrad, Inc., "Stellant CT Injection System", Operation Manual Catalog #SOM 700 EN, 2003, 88 pages - hereafter, "Stellant"

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 57-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emig et al (6471674) in view of Medrad, Inc., "Stellant CT Injection System", Operation Manual Catalog #SOM 700 EN, 2003, 88 pages - hereafter, "Stellant".
2. Emig et al discloses a method of using a dual head injector (Fig 1), the method comprising: mounting a first syringe that is prefilled (300, col 2, lns 19-20; col 5, lns 38) with contrast media to the injector; mounting a second syringe to the injector (500); coupling a first section of T-tubing (450) to the first syringe and coupling a second section of the T-tubing to the second syringe (Fig 2a-f); initiating a purging operation of the injector while the first and second syringes are mounted to the injector and while the first and second sections of the T- tubing are coupled to the first and second syringes

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(col 6, lns 9-19); initiating a purging operation of the injector while the first and second syringes are mounted to the injector and while the first and second sections of the T-tubing are coupled to the first and second syringes (Fig 2a-f; col 6, lns 6-18), respectively, wherein the first syringe comprises contrast media (300) prior to the initiation of the purging operation; wherein the second syringe comprises saline prior to the initiation of the purging operation; wherein the purging operation comprises: advancing a first plunger drive ram of the injector to move a plunger of the first syringe to a first stop point at the intersection of the T-valve where the check valve and where the plunger of the first syringe stops (Fig 2a-f; col 6, lns 6-18; wherein the plunger 320 is preferably advanced sufficiently to prime the fluid path between syringe 300 and check valve 410), wherein the advancing of the first plunger drive ram purges all air from the first syringe and the first section of Y-tubing and fills the first section of the Y-tubing with contrast media (Fig 2a-f; col 6, lns 6-18; wherein the plunger 320 is preferably advanced sufficiently to prime the fluid path between syringe 300 and check valve 410); and advancing a second plunger drive ram of the injector to move a plunger of the second syringe to a second stop point where the plunger of the second syringe stops (Fig 2a-f; col 6, lns 6-18; wherein the second stop clears everything with saline), wherein the advancing of the second plunger drive ram purges air from the second syringe and the second section and third sections of the T-tubing and fills it with saline (Fig 2a-f; col 6, lns 6-18); and initiating an injection procedure that includes injecting contrast media into the patient (col 6), wherein the injection procedure occurs: after the purging operation is completed; while the first and second syringes are mounted to the injector; and while

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the first and second sections of the Y-tubing are coupled to the first and second syringes, respectively (Fig 2a-g); wherein a combination of the advancing of the first plunger drive ram and the advancing of the second plunger drive ram results in a purge of substantially all air from the first and second syringes and the T-tubing (col 6); wherein the advancing of the second plunger drive ram comprises filling the second section of the Y-tubing with saline; wherein the advancing of the second plunger drive ram comprises filling the second section and a third section of the Y-tubing with saline (Fig 2a-f; col 6, Ins 6-18); wherein the first syringe is filled with contrast media (300); wherein the second syringe comprises saline prior to initiating the purging operation (500).

3. However, Emig et al does not disclose a Y-connector.

4. Stellant teaches that it is known to have a Y-connector in a dual head injector system for the purpose of merging two flows into a single flow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the T-connector as taught by Emig et al with the Y-connector as taught by Stellant for the purpose of merging two flows because they perform substantially the same function in substantially the same manner.

5. Additionally, it is not clear if Emig et al in view of Stellant explicitly disclose wherein the advancing of the first plunger drive ram occurs before the advancing of the second plunger drive ram (see Emig et al, col 6, Ins 6-19; Applicant's Remarks, pg 7-8).

6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the purge protocol as taught by Emig et al with a the first

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plunger drive ram occurring before the advancing of the second plunger drive ram since changes in sequence are *prima facie* obvious in the absence of new or unexpected results (See MPEP 2144.04(IV)(C)). Having the first plunger drive ram advancing before the second plunger drive ram does not provide a new or unexpected result in this case. It is apparent that the expected result of priming the contrast syringe and tubing will occur first, followed by the priming of the saline syringe and tubing. Furthermore, under the *KSR* exemplary rationales that may support a conclusion of obviousness, the switching of the advancement of the first and second plunger drive rams are combining prior art elements according to known methods to yield predictable results through the use of known techniques and, finally, is also “obvious to try” because the choice of advancing the first vs. second plunger drive ram to prime the device with either the saline or contrast syringe first followed by priming with the other syringe is a choice from a finite number of identified, predictable solutions, with a reasonable expectation of success (see MPEP 2141).

(10) Response to Argument

- 1. The Appellant argues that no ordering of the saline prime and the contrast prime is explicitly set forth in Emig (Br. at 9, ¶1) and the Examiner’s rationale that there are only two options for undertaking a purging option 1) a saline push followed by a contrast push; or 2) a contrast push followed by a saline push is in error (Br. at 11, ¶2). The Appellant has set forth a specific purging operation and one skilled in the art would not be motivated to modify the teachings of Emig and/or Stellant in any manner to arrive at the Appellant’s invention of claim 57 and 71 (Br. at 12, ¶1).**

In response to (1), the Examiner respectfully disagrees. Emig et al explicitly discloses that there are two options for undertaking a purging operation to prime the injection system for contrast injection.

In FIG. 2C, forward motion of plunger 520 causes saline to flow through the fluid path, including tubing 430 and patient interface 200, as represented by the solid flow arrows. Such "priming" of the fluid delivery path with saline is preferred, for example, to remove air from the fluid path and minimize wastage of contrast medium. Check valve 410 prevents saline from entering contrast syringe 300. Plunger 320 of contrast syringe 300 is also preferably advanced sufficiently to prime the fluid path between syringe 300 and check valve 410 for injection of contrast. In that regard, a small amount of contrast can be injected into the fluid path as illustrated by the dashed flow arrows in FIG. 2C to remove any air between syringe 300 and check valve 410.

(17) After priming of fluid delivery system 100 as described above, the patient interface 200 is connected to the patient by means of, for example, a catheter. An operator may then, for example, begin a slow flow of saline to assist in assuring that the vein in which the catheter (not shown) is placed remains open (sometime referred to as a keep-vein-open or KVO process). Before injection of contrast, the flow of saline is preferably stopped. (emphasis added)
(col 6, lns 6-26)

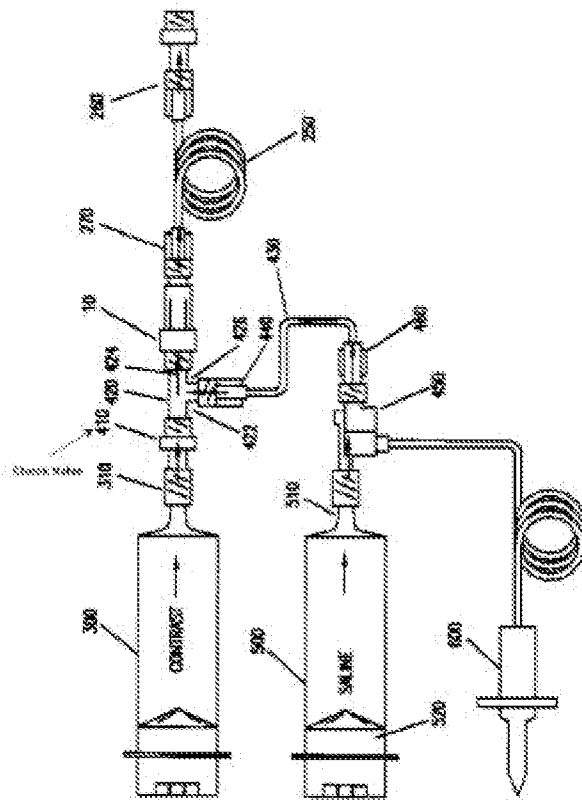


FIG. 2C

Here, Emig et al discloses that purging of air from the fluid lines is accomplished by a saline push and a contrast push but is silent as to the order of the steps. Thus, the explicit teachings of Emig et al require either one of two choices: 1) a saline push followed by a contrast push; or 2) a contrast push followed by a saline push.

Emig et al discloses a check valve (410) that “prevents saline from entering contrast syringe 300” and which acts as a limit for the contrast push (“the Plunger 320 of contrast syringe 300 is also preferably advanced sufficiently to prime the fluid path between syringe 300 and check valve 410 for injection of contrast. In that regard, a

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small amount of contrast can be injected into the fluid path as illustrated by the dashed flow arrows in FIG. 2C to remove any air between syringe 300 and check valve 410”).

One of ordinary skill in the art would recognize that Emig et al could function under either of: 1) a saline push followed by a contrast push; or 2) a contrast push followed by a saline push. In option (1), the check valve (410) would prevent saline from entering the contrast syringe. In option (2), the contrast push is made up to the check valve (410) and the subsequent saline push would not disrupt the contrast push because the check valve (410) would prevent the saline from entering the flow line (i.e. 310) and the contrast syringe (300). Thus, Emig et al explicitly discloses two limited options for the method of priming the contrast injection device and purging air and Emig et al would function for its intended purpose and operate properly under either of the two options. Contrary to the Appellant’s assertions, Emig et al does not disclose a vast option set for configuring a purging operation. Emig et al discloses two options and option (2): a contrast push followed by a saline push is the same order as claimed by the Appellant. Given the limited number of options for the order of addition of saline and contrast, as described in the rejection above, the examiner maintains the position that it would have been obvious to push the contrast first followed by a saline push.

For at least the reason, the Board must affirm the Examiner’s rejection.

2. The Appellant argues that the Examiner’s reliance upon MPEP § 2144.04(IV)(c) is inappropriate because the Appellant has provided criticality for the specific purging order and is not directed to “adding ingredients.” (Br. at 12, ¶2-4).

In response to (2), the Examiner respectfully disagrees. First, the Appellant does not mention “waste,” “expense,” or “simple” in the specification as originally filed. Simply

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put, the Appellant lacks support for the purported criticality in the originally filed specification. Consequently, the Board should disregard the Appellant's purported criticality. Second, the Examiner notes, that the Appellant's statement of criticality may be correct, because Emig et al discloses the exact reasoning and criticality for Emig et al's disclosed air purging steps, see "Such "priming" of the fluid delivery path with saline is preferred, for example, to remove air from the fluid path and minimize wastage of contrast medium" (emphasis added) (cited from above excerpt). The Appellant has not provided new or unexpected results by the method claimed in claims 57 and 71.

The Appellant next attempts to argue MPEP §2144.04(IV)(c) is inapplicable on its face because the Appellant's claims are not directed to "adding ingredients." This is not persuasive. MPEP § 2144.04(IV)(c) states:

Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

As disclosed, the cases cited in 2144.04(IV)(c) are directed to processes and the obviousness of ordering of the known steps within that process. "Adding ingredients" refers to the adding of elements that form the steps of the process. Here, Emig et al

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discloses steps that “add[ing] ingredients” to the process. Namely, Emig et al discloses two options of a method of adding contrast then saline or saline then contrast to a fluid tubing set to purge air from the tubing to prepare for an injection. As set forth in 2144.04(IV)(C) where there is no new or unexpected results, the selection of any order of the performing of process steps is *prima facie* obvious. The Appellant has not disclosed new or unexpected results. Thus, to one of ordinary skill in the art is it *prima facie* obvious to select any order (i.e. select either option (1) or option (2)) of the air purging process steps disclosed in Emig et al.

Thus, it would have been obvious to one of ordinary skill in the art to first perform the contrast purging step, where contrast injector ram pushes contrast through the tubing system up to the check valve (410), and then perform the saline purging step. For at least this reason, the Board must affirm the Examiner’s rejection.

3. The Appellant argues that the Examiner’s “merely the result of combining prior art elements according to known methods” is improper because the method steps of the purging operation of claim 57 and 71 are not known.” (Br. at 13, ¶2).

In response to (3), the Examiner respectfully disagrees. First, the Examiner finds that the method steps of the purging operation are known and explicitly taught by Emig et al. For example, Emig et al discloses the method step of purging air from the tubing connecting the contrast syringe to the T-connector by pushing contrast up until the check valve (410).

Plunger 320 of contrast syringe 300 is also preferably advanced sufficiently to prime the fluid path between syringe 300 and check valve 410 for injection of contrast. In that regard, a small amount of contrast can be injected into the fluid path as illustrated by

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the dashed flow arrows in FIG. 2C to remove any air between syringe 300 and check valve 410. (col 6, lns 12-18)

This meets the Appellant's limitation of purging air from the first syringe and the first section of tubing up to the intersection of the first, second, and third sections of tubing with contrast media (this occurs at the T-connector, downstream of the check valve 410).

Further, Emig et al discloses the method step of purging air from the second syringe, the second section of the connector, the intersection of the first, second, and third sections of the connector (T-connector disclosed by Emig et al, modified to be a Y-connector as taught by the Stellant reference) with saline.

In FIG. 2C, forward motion of plunger 520 causes saline to flow through the fluid path, including tubing 430 and patient interface 200, as represented by the solid flow arrows. Such "priming" of the fluid delivery path with saline is preferred, for example, to remove air from the fluid path and minimize wastage of contrast medium. Check valve 410 prevents saline from entering contrast syringe 300. (col 6, lns 6-12)

The order of such known steps is not explicitly taught by Emig et al. However, as discussed above, Emig et al can perform its intended purpose under either ordering of its disclosed contrast and saline pushes and one of ordinary skill in the art would find it *prima facie* obvious to order the contrast/saline pushes in any order, including a contrast push followed by a saline push as claimed by the Appellant. Thus, for at least this reasons, the Board must affirm the Examiner's rejection.

4. The Appellant argues that the Examiner's "obvious to try" rationale is improper because the Examiner failed to present

findings as required to support the rationale and there is not a finite number of identified predictable solutions that exist.” (Br. at 14, ¶3).

In response to (3), the Examiner respectfully disagrees. First, the Examiner has set forth rationale sufficient to support an “obvious to try” rationale. The recognized need in the art is to purge air from tubing of contrast injection systems without wasting contrast solution (see Emig et al., col 6, lns 9-11, cited above). The finding that there are a finite number of identified, predictable solutions to the recognized need in the art is shown by Emig et al.’s explicit disclose of two options for performing an air purge: 1) a saline push followed by a contrast push; or 2) a contrast push followed by a saline push (see above discuss in response to (1)). The finding that one of ordinary skill in the art could have pursued the known potential solutions (i.e. option 1 or 2) with a reasonable expectation of success is shown first by the fact that Emig et al could perform its intended purpose under either option (1) or (2). Also, having the first plunger drive ram advancing before the second plunger drive ram does not provide a new or unexpected results in this case. One of ordinary skill in the art would find the expected result of performing the priming the contrast syringe and tubing first to be contrast moving up to the check valve (410) in Emig et al, and the expected result of performing the saline push to prime saline syringe and tubing to also be apparent.

Finally, the expected result of performing the saline push second and stopping the saline push at the junction of check valve (410) or at any point downstream of check valve (410) would have been obvious to one of ordinary skill in the art because one of ordinary skill in the art could have selected that stop point with an expectation of

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success based on the explicit disclosure of Emig et al. For example, as cited above, after the priming to remove air, an operator may then begin a slow flow of saline to assist to keep the vein open, prior to stopping the flow of saline to perform an injection of contrast (col 6, lns 19-26). One of ordinary skill would have an expectation of success for stopping the saline push at any point downstream of the check valve (410) because the check valve (410) prevents the saline from disrupting the contrast solution in the tubing and contrast syringe (300) and Emig et al discloses delivering a slow flow of saline for a period and then stopping flow prior to performing a contrast injection.

Thus, for at least these reasons, the Examiner has presented finding to support an "obvious to try" rationale and Emig et al explicitly discloses a finite number of identified solutions to purging air in the form of two options for ordering contrast/saline pushes. Thus, the Board must affirm the Examiner's rejection.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Andrew M Gilbert/

Examiner, Art Unit 3767

Conferees:

/Theodore J Stigell/

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Primary Examiner, Art Unit 3763

/Janet C. Baxter/

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